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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/617,078

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Steven P. Schwendeman

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EXAMINER

BETTON, TIMOTHY E

ART UNIT

PAPER NUMBER

1614

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/27/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/617,078

Applicant(s)

SCHWENDEMAN ET AL.

Examiner

Timothy E. Betton

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 7-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election with traverse in the reply filed on 12 October 2006 is acknowledged. The traversal is on the ground(s) that restriction is not proper in this instance. This is not found persuasive because Examiner has met the two criteria for a proper restriction between patentably distinct inventions, which are, restriction based on the independence and/or distinctness of claimed invention and the necessity for restriction based on serious search burden on Examiner.

Applicants disclose MPEP§ 803, which explicitly states that "if the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to independent or distinct inventions." Criteria have sufficiently been met for a proper restriction requirement, therefore, Applicants' traverse is not found persuasive.

Election/Restriction

Applicants' election of group I which is drawn to a polymeric delivery system consisting of poly (D-L-lactide-co-glycolide) (PGLA), the antigen which is disclosed as a peptide, and the basic additive is disclosed as magnesium carbonate. Claims 1-6 are thus readable on this election.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections 35 U.S.C. 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

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Claim 4 is rejected under 35 U.S.C. § 112, second paragraph, as being vague and indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claimed value range for solubility in water in claim 4 is a relative value range, which renders the claim vague and indefinite. The value range is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Instant claim 4 discloses a claimed value range for the solubility in water, however the disclosure contains no units to yield a proper and specific limitation to the claimed value ranges. The specification fails to particularly point out and distinctly claim the subject matter, i.e., the solubility in water value of basic additive in claim 4. There, said value ranges of claim 4 are vague and indefinite.

Claim Rejections 35 U.S.C. §, 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andrianov et al. (USPN 5529777) in view of Sokoll et al (USPN 6228423 B1).

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Andrianov et al teach water soluble polymers or polymeric hydrogels [which] are used to encapsulate antigen to form vaccines. The antigen is mixed with a polymer solution, microparticles are formed of the polymer and antigen, and, optionally, the polymer is crosslinked to form a stable microparticle. Preferred polymers are alginate and polyphosphazenes, and mixtures thereof. Microparticles can be administered parenterally or mucosally. For oral delivery, the microparticles are preferably fifteen microns or less in diameter, and adhere to the mucosal lining of the gastrointestinal tract, increasing uptake by the reticuloendothelium.

Andrianov et al. teach a polymeric/antigen delivery system (PLGA), that is biodegradable and biocompatible as also disclosed in subject claim1 (Column 4, lines 11-53). Further, Andrianov et al. teach an antigen as a peptide in Column 12, line 29 of referenced patent as also disclosed in instant claims 2 and 3.

Additionally, Andrianov et al. teach a practicing method to elicit an immunogenic response incorporating said PLGA as is also disclosed in instant claim 1.

Furthermore, Andrianov et al. teach magnesium as a basic additive/multivalent cation incorporated with a polyelectrolyte preparation.

Andrianov et al. does not teach the basic additive of magnesium carbonate. However, Examiner refers to Sokoll et al., which teach the immunogenic compositions comprising microparticles formed according to the present invention may be delivered in a manner to elicit an immune response at mucosal surfaces. Thus, the immunogenic composition may be administered to

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mucosal surfaces by nasal, oral (intragastric), buccal or rectal routes. Oral formulations may include normally employed excipients, such as pharmaceutical grades of saccharin, cellulose and magnesium carbonate.

Thus, it would be *prima facie* obvious to one of ordinary skill in the art to modify the invention of Andrianov et al. to accommodate the disclosure of magnesium carbonate in the formulation as in Sokoll et al. Both referenced patents teach a PLGA directed to delivery of an antigen to a specific region in a mammal. Therefore, it would at once have been obvious to combine both references due to their relative similarity in scope of invention, i.e., delivery of antigen by a polymeric delivery system.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schoch, E.P. (Industrial and Engineering Chemistry; Direct Titrometric Methods for Magnesium, Calcium, and Sulfate Ions and Their Application in Water Analysis; 1926, Vol. 19, No.1, page 112) and CHEMTUTOR, LLC Acids and Bases; The 5% Rule, Copyright 1997, (page 17) in view of Lenntech (Magnesium (Mg) and water; Chemical Properties, Health and Environmental effects; Copyright 1998, page 1).

Schoch, E.P. teaches well-established pH value ranges for magnesium and magnesium ion at a pH of 10.23 as is encompassed in subject genus claim 4 of a pH of about 6.8 to about 12.5 for the basic additive of magnesium derivative/ pharmacological salt.

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Schoch does not teach the method of instant claim 1 wherein the basic additive is characterized by having a pH of a saturated solution at 37 degrees Celsius but instead at 90-100 degrees Celsius (page1, 1st paragraph).

CHEMTUTOR, LLC teach the measurement of pH in medicine, for instance must be at 37 degrees Celsius, (page 17).

CHEMTUTOR, LLC does not teach magnesium carbonate, but does teach derivatives of magnesium and derivatives of carbonates. However, Examiner refers to Lenntech, which teaches water solubility of magnesium carbonate as being more soluble at (600mg/L) in comparison to magnesium hydroxide at (12 mg/L)(page 1, 4th paragraph). It further teaches that magnesium metals are not affected by water at room temperature and that magnesium generally is a slow-reacting element, but reactivity increases with oxygen levels (page 1, second paragraph).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the art disclosed in Schoch with that of CHEMOTUTOR, LLC. The teaching of properties and characteristics of magnesium carbonate in Lenntech would be the motivation to further combine the references of Schoch, CHEMOTUTOR, LLC and Lenntech. Claim 4 is directed to values, characteristics, and properties of magnesium carbonate already well-established in the pertinent art.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TEB

 12/18/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER